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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PDL BIOPHARMA, INC. and EKR THERAPEUTICS, INC., Plaintiffs, v. SUN PHARMACEUTICAL INDUSTRIES LTD., Defendant.	Honorable Katherine S. Hayden, U.S.D.J. Civil Action No. 07 CV 1788 (KSH) (PS) **DEFENDANT SUN PHARMACEUTICAL INDUSTRIES LTD.'S ANSWER TO THE SECOND AMENDED COMPLAINT, AFFIRMATIVE DEFENSES AND COUNTERCLAIM**

Defendant Sun Pharmaceutical Industries Ltd. ("Sun") by way of Answer to Plaintiffs PDL BioPharma, Inc.'s ("PDL") and EKR Therapeutics, Inc.'s Second Amended Complaint For Patent Infringement, states as follows:

AS TO THE PARTIES

1. Sun is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 1, and therefore denies the same.

2. Sun is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 2, and therefore denies the same.

3. Sun admits that it is an Indian corporation having a place of business at Acme Plaza, Andheri Kurla Road, Andheri (East), Mumbai 400 059, India. Sun denies the remaining allegations of Paragraph 3.

AS TO THE NATURE OF THE ACTION

4. Paragraph 4 contains legal conclusions to which no answer is required. To the extent an answer is required, Sun admits that PDL's and EKR's Second Amended Complaint alleges infringement of U.S. Patent No. 5,164,405 ("the '405 patent") under the patent laws of the United States. Sun specifically denies that PDL and EKR are entitled to any relief pursuant to their Second Amended Complaint.

AS TO JURISDICTION AND VENUE

5. Paragraph 5 contains legal conclusions to which no answer is required. To the extent an answer is required, Sun admits that this Court has subject matter jurisdiction over PDL's and EKR's patent infringement claims. Sun specifically denies that PDL and EKR are entitled to any relief pursuant to their Second Amended Complaint.

6. Paragraph 6 contains legal conclusions to which no answer is required. To the extent an answer is required, Sun admits that it is in the business of, *inter alia*, manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Sun denies that Sun Pharmaceutical Industries, Inc. ("Sun USA")—Sun's wholly-owned subsidiary—is an agent or alter-ego of Sun, and further denies that it manufactures, markets and sells generic drugs throughout the United States and in this judicial district through Sun USA, or otherwise conducts business through Sun USA. Sun further denies that it leases and owns facilities in this judicial district or that it retains a registered agent in this judicial district. Further

responding, Sun consents to this Court's personal jurisdiction for purposes of the present litigation only. Sun denies the remaining allegations of Paragraph 6.

7. Paragraph 7 contains legal conclusions to which no answer is required. To the extent an answer is required, Sun admits that venue is proper in this judicial district.

AS TO CLAIM FOR RELIEF
(PATENT INFRINGMENT U.S. PATENT NO. 5,164,405)

8. Sun realleges and incorporates by reference its responses to Paragraphs 1-7 as if fully set forth herein.

9. Sun admits that the face of the '405 patent indicates that it is entitled "Nicardipine pharmaceutical composition for parenteral administration" and that the '405 patent issued on November 17, 1992. Sun specifically denies that the '405 patent was duly and legally issued. Further responding, Sun admits that a copy of the '405 patent was attached as Exhibit A to the Second Amended Complaint.

10. Paragraph 10 contains legal conclusions to which no answer is required. To the extent an answer is required, Sun is without information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 10, and therefore denies the same.

11. Paragraph 11 contains legal conclusions to which no answer is required. To the extent an answer is required, Sun is without information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 11, and therefore denies the same.

12. Paragraph 12 contains legal conclusions to which no answer is required. To the extent an answer is required, Sun is without information sufficient to form a belief as to the truth or falsity of the allegations that EKR is the is the holder of NDA 19-734 or that said NDA was approved by the FDA on January 30, 1992. Sun admits, upon information and belief, that the '405 patent is listed in the Orange Book.

13. Sun admits, upon information and belief, the allegations of Paragraph 13.

14. Paragraph 14 contains legal conclusions to which no answer is required. To the extent an answer is required, Sun is without information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 14, and therefore denies the same.

15. Sun admits, upon information and belief, the allegations of Paragraph 15.

16. Paragraph 16 contains legal conclusions regarding the scope of the claims of the '405 patent to which no answer is required. To the extent an answer is required, Sun denies the allegations of Paragraph 16.

17. Sun admits the allegations of Paragraph 17.

18. Sun admits the allegations of Paragraph 18.

19. Sun admits that it sent to PDL a Notice of Certification dated March 2, 2007, for Sun's ANDA No. 78-405 pursuant to 21 U.S.C. §§ 355(j)(2)(B)(i) and (ii). Sun further admits that its Paragraph IV Certification to its ANDA No. 78-405 alleges that the claims of the '405 patent would not be infringed by the manufacture, use or sale of Sun's proposed ANDA product, either literally or under the doctrine of equivalents.

20. Sun admits the allegations of Paragraph 20.

21. Sun denies the allegations of Paragraph 21.

22. Sun admits that filing an ANDA containing a Paragraph IV Certification to an Orange Book listed patent vests this Court with subject matter jurisdiction pursuant to 35 U.S.C. § 271(e) as to that patent. Sun denies the remaining allegations of Paragraph 22, including any implication that the '405 patent is valid and/or enforceable.

23. Sun denies the allegations of Paragraph 23.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

The manufacture, use, or sale of the product that is the subject of Sun's ANDA No. 78-405 has not infringed, does not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '405 patent, either literally or under the doctrine of equivalents.

SECOND AFFIRMATIVE DEFENSE

The claims of the '405 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112.

THIRD AFFIRMATIVE DEFENSE

Any additional defenses or counterclaims that discovery may reveal.

COUNTERCLAIM FOR DECLARATORY JUDGMENT

Defendant Sun Pharmaceuticals Industries Ltd. ("Sun"), by way of Counterclaim against Plaintiffs PDL BioPharma, Inc. ("PDL") and EKR Therapeutics, Inc. ("EKR"), states as follows:

PARTIES

1. On information and belief, PDL is a publicly held corporation organized and existing under the laws of the State of Delaware, having its headquarters at 34801 Campus Drive, Fremont, California 94555.

2. On information and belief, EKR is a privately held company organized and existing under the laws of the State of Delaware, having its headquarters at 7 East Frederick Place, Cedar Knolls, New Jersey 07927.

3. Sun is a corporation organized and existing under the laws of India, having its principal place of business at Acme Plaza, Andheri Kurla Road, Andheri (East) Mumbai, 400 059, India.

BACKGROUND

A. FDA Approval of New Brand-Name Drugs.

4. The Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Hatch-Waxman Amendments, sets forth the rules that the Food and Drug Administration ("FDA") follows when considering whether to approve both brand-name and generic drugs.

5. Under the Hatch-Waxman Amendments, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by FDA. *See* 21 U.S.C. § 355.

6. An NDA must include, among other things, the number of any patent that claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. §§ 355(b)(1) and (c)(2); 21 C.F.R. §§ 314.53(b) and (c)(2).

7. Upon approval of the NDA, the FDA publishes patent information for the approved drug in "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A)(iii).

B. Generic Competition – Abbreviated New Drug Applications ("ANDAs").

8. Generic drugs are versions of brand-name prescription drugs that typically contain the same active ingredients, but not necessarily the same inactive ingredients as the brand-name original.

9. Before 1984, a company that wished to make a generic version of an FDA-approved drug had to file an application containing new studies showing the already-approved drug's safety and effectiveness. Preparing such an application was as time-consuming and costly as the original NDA.

10. In 1984, however, Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments. *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156 and 271(e)). Congress passed the Hatch-Waxman Amendments, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition. Under the Hatch-Waxman Amendments, a generic manufacturer submits what is called an Abbreviated New Drug Application ("ANDA").

11. To receive approval of its ANDA, an applicant must show that its generic drug is "bioequivalent" to the listed reference drug. *See* 21 U.S.C. § 355(j)(4)(F).

12. When filing an ANDA seeking approval of a generic version of a drug listed in the Orange Book, the ANDA applicant must also "certify" that any patent information listed in the Orange Book does not preclude FDA approval of the ANDA applicant's generic version of the drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

13. A so-called "Paragraph IV" Certification asserts that the listed patent is invalid, unenforceable, and/or will not be infringed and, on that basis, seeks FDA approval of the generic product prior to patent expiration. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

14. An applicant submitting an ANDA containing a Paragraph IV Certification must notify both the patent holder and NDA holder of its Paragraph IV Certification. *See* 21 U.S.C. § 355(j)(2)(B)(i).

15. Upon receiving notice of the Paragraph IV Certification, the patent holder has 45 days in which to file an infringement suit against the generic manufacturer. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. § 271(e)(2)(A).

16. Patent holders have a significant strategic incentive to file suit because doing so, regardless of merit, prevents the FDA from approving the generic maker's ANDA for a period of 30 months. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

17. If the court hearing the infringement action decides the patent is valid, enforceable, and would be infringed by the product proposed in the ANDA, the FDA will not approve the ANDA until the patent expires. *See* 21 U.S.C. § 355(j)(5)(B)(iii). If, however, the court hearing the infringement action rules before the expiration of the 30-month period that the patent is invalid, unenforceable, and/or not infringed, the FDA may approve the ANDA. *Id.*

C. Sun's Injectable Nicardipine Hydrochloride ANDA.

18. Sun filed an ANDA No. 78-405 with the FDA seeking generic approval for an injectable nicardipine hydrochloride drug product containing as the active ingredient nicardipine hydrochloride in 2.5 mg/ml strength. The ANDA shows that Sun's proposed injectable nicardipine hydrochloride drug product is bioequivalent to the injectable nicardipine hydrochloride drug product that is the subject of NDA No. 019734.

19. Because Sun seeks FDA approval to market its generic injectable nicardipine hydrochloride drug product before expiration of the patent that PDL listed in the Orange Book, Sun's ANDA includes a Paragraph IV Certification to U.S. Patent No. 5,164,405 ("the '405 patent").

D. U.S. Patent No. 5,164,405

20. The '405 patent states on its face that it was issued on November 17, 1992 to Calum B. McFarlane, Alistair B. Selkirk and Michael J. Dey and assigned to Syntax (U.S.A.), Inc. On information and belief, PDL is a past owner and EKR is the current owner of the '405 patent, which is scheduled to expire no later than November 17, 2009.

21. PDL and EKR continue to list the '405 patent in the Orange Book in connection with NDA No. 019734.

22. In order to have the '405 patent listed in the Orange Book, the law required PDL and EKR to certify to the FDA, under oath, that the '405 patent claims the "drug" nicardipine hydrochloride or a "method of using" nicardipine hydrochloride and is a patent for which a claim of patent infringement could reasonably be asserted against an authorized party.

23. By bringing suit against Sun, PDL and EKR have taken active steps to block Sun's attempt to launch a generic 2.5 mg/ml injectable nicardipine hydrochloride drug product.

24. The claims of the '405 patent are invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of Sun's 2.5 mg/ml injectable nicardipine hydrochloride drug product.

25. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Sun and PDL and EKR as to liability for infringement of the '405 patent.

JURISDICTION AND VENUE

26. Sun realleges and incorporates by reference the allegations of Paragraphs 1-25 as if fully set forth herein.

27. Present, genuine, and justiciable controversies exist between Sun and PDL and EKR regarding the '405 patent.

28. Subject matter jurisdiction over this counterclaim is proper under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

29. Venue is proper under 28 U.S.C. §§ 1391 and 1400.

FIRST COUNT
Declaration of Non-Infringement of the '405 Patent

30. Sun realleges and incorporates by reference the allegations of Paragraphs 1-29 as if fully set forth herein.

31. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that the claims of the '405 patent will not be infringed by the manufacture, use or sale of Sun's 2.5 mg/ml injectable nicardipine hydrochloride drug product.

32. A present, genuine and justiciable controversy exists between Sun and PDL and EKR regarding, *inter alia*, the issue of whether the manufacture, use or sale of Sun's 2.5 mg/ml injectable nicardipine hydrochloride drug product would infringe one or more claims of the '405 patent.

33. The manufacture, use or sale of Sun's 2.5 mg/ml injectable nicardipine hydrochloride drug product would not infringe any valid and/or enforceable claim of the '405 patent.

34. Sun is entitled to a declaration that the manufacture, use or sale of Sun's 2.5 mg/ml injectable nicardipine hydrochloride drug product would not infringe any valid and/or enforceable claims of the '405 patent.

SECOND COUNT
Declaration of Invalidity of the '405 Patent

35. Sun realleges and incorporates by reference the allegations of Paragraphs 1-34 as if fully set forth herein.

36. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that claims of the '405 patent are invalid.

37. A present, genuine, and justiciable controversy exists between Sun and PDL and EKR regarding, *inter alia*, the validity of the claims of the '405 patent.

38. The claims of the '405 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112.

39. Sun is entitled to a declaration that the claims of the '405 patent are invalid.

REQUEST FOR RELIEF

WHEREFORE, Defendant Sun Pharmaceutical Industries Ltd. respectfully requests that this Court enter a Judgment and Order in its favor and against Plaintiffs PDL BioPharma, Inc. and EKR Therapeutics, Inc. as follows:

(a) declaring that Sun has not infringed any valid and enforceable claim of U.S. Patent No. 5,164,405;

(b) declaring that the claims of U.S. Patent No. 5,164,405 are invalid;

(c) declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Sun its attorneys' fees, costs and expenses in this action; and

(d) awarding Sun any further and additional relief as the Court deems just and proper.

WINSTON & STRAWN, LLP
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By: _____
James S. Richter

Dated: May 28, 2008

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CERTIFICATE OF SERVICE

I hereby certify that on May 28, 2008 I served the foregoing **SUN'S ANSWER TO PLAINTIFFS' SECOND AMENDED COMPLAINT, AFFIRMATIVE DEFENSES AND COUNTERCLAIM** to the following counsel of record by ECF and email:

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Dated: May 28, 2008